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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,286	08/24/2007	Benedict Marie Doorschodt	0470-053534	8521

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,286	Applicant(s) DOORSCHODT, BENEDICT MARIE	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/27/07</u> . | 6) <input type="checkbox"/> Other: ____. |

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the five break locations, and the distance between the break locations must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 3736

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14, 18, 19, 21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regards to Claim 14, the claim recites "...relatively soft at temperatures between 35 °C and 40 °C and in contact with moisture". The current specification does not disclose this limitation.

With regards to Claim 18, the claim recites "at least two break points", while the current specification as well as the drawings only support two break points.

Furthermore, the claim recites "...being 10mm", while the current specification only supports 15mm.

With regards to Claim 19, the claim recites "...having at least five break locations", while the current specification as well as the drawings only support two break locations.

With regards to Claim 21, the claim recites "the distance between break locations is 3-10mm", while the specification only supports 3-7mm.

With regards to Claim 23, the claim recites "0.1-1.5mm", while the specification only supports 0.5-1.5mm.

With regards to Claim 24, the claim recites the “rings are made of a blood-staunching material”. The current specification does not support this limitation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 13, 14 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Garcia (2003/0097079 A1).

Garcia discloses a biopsy needle sheath and further discloses an insertion instrument and a sleeve of bioabsorbable material guiding the instrument; the sleeve being made of a material that is relatively rigid outside the body and becomes softer after the introduction into the body and collapses onto itself when the instrument is withdrawn; the sleeve is made of a material that is relatively rigid below 30 °C and not in contact with water and is relatively soft at temperatures between 35-40 °C and in contact with moisture; and the sleeve has blood staunching properties on the outside. See Paragraphs 0032, 0060, 0067, 0076, 0080, 0083, 0085, 0089 and 0094.

Claim Rejections - 35 USC § 103

Art Unit: 3736

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia (2003/0097079 A1) as applied to claim 13 above, and further in view of Barrows (6,884,427 B1).

Garcia, as discussed above, discloses a bioabsorbable sheath but fails to disclose the type of material; and the material is a combination of polyglycolide, polylactic acid and caprolactone in certain percentages.

Barrows discloses a means for introducing agents into the body and further discloses the type of material; and the material is a combination of polyglycolide, polylactic acid and caprolactone in certain percentages. See Column 6, lines 42-53.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Garcia to include the specific composition of the bioabsorbable sheath, as per the teachings of Barrows, since it is well known in the art to utilize such compounds as polylactic acid, polyglycolide and caprolactone in a bioabsorbable device. Furthermore, it would have been obvious to one of ordinary skill in the art to obtain the specific percentages of the compounds in a combination through routine experimentation.

8. Claims 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia (2003/0097079 A1) as applied to claim 13 above, and further in view of Haaga (4,838,280).

Garcia, as discussed above, discloses a bioabsorbable sheath, and further discloses the sheath is designed for direct contact with the insertion instrument and the body; the sleeve comprises a continuous base sleeve of flexible material and a number of rings arranged around it; and the sleeve has a thickness of 0.1-1.5mm.

Garcia however fails to disclose the sleeve has break points at a distance from the distal end of the sleeve.

Haaga discloses a hemostatic sheath and further discloses the sleeve has break points at a distance from the distal end of the sleeve. See Column 11, lines 14-20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Garcia to include the use of at least one break point, as per the teachings of Haaga, since it would provide a means of separating the hemostatic sleeve from the device during withdrawal from the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Primary Examiner, Art Unit 3736